

IN THE CLAIMS:

Kindly amend claims 1-3, 11 and 16 as follows:

1. (Currently Amended) An immunoassay reagent for use in a quantitative determination of a target antigen or antibody present in a sample, said reagent consisting essentially of the following components:

(a) an insoluble carrier which carries and is coupled to an enzyme and an antibody or antigen reactive with said target antigen or antibody, said insoluble carrier comprising at least one selected from the group consisting of an organic polymer powder ~~article~~ particle, microorganism, blood cell and cell membrane fragment, said insoluble carrier being capable of aggregation;

(b) an enzyme inhibitor for reacting with and inhibiting activity of said enzyme, said enzyme inhibitor being in a free state uncoupled to an antigen or antibody and being increasingly ~~unhindered~~ hindered from reacting with said enzyme when said insoluble carrier is increasingly agglutinated; and

(c) a substrate for the enzyme capable of producing an optically detectable indication of reaction with the enzyme, wherein said substrate is not hindered from reacting with said enzyme when said enzyme is unreacted with said enzyme inhibitor when said insoluble carrier is increasingly aggregated, said components (a) - (c) being maintained separate and apart and mixed together only with a sample containing the target antigen or antibody.

2. (Currently Amended) An immunoassay reagent for use in a quantitative determination of a target antigen or antibody present in a sample, said reagent consisting essentially of the following components:

(a) an insoluble carrier which carries and is coupled to an enzyme and an antibody or antigen reactive with said target antigen or antibody, said insoluble carrier comprising at least one selected from the group consisting of an organic polymer powder ~~article~~ particle, microorganism, blood cell and cell membrane fragment, said insoluble carrier being capable of aggregation;

(b) an enzyme inhibitor for reacting with and inhibiting activity of said enzyme, said enzyme inhibitor being in a free state uncoupled to an antigen or antibody and being increasingly hindered from reacting with said enzyme once ~~that~~ said insoluble carrier is increasingly agglutinated; and

(c) a substrate for the enzyme capable of producing an optically detectable indication of reaction with the enzyme, wherein said substrate is not hindered from reacting with said enzyme when said enzyme is unreacted with said enzyme inhibitor when said insoluble carrier is increasingly aggregated, said immunoassay reagent consisting of a first reagent and a second reagent, wherein said first reagent contains said insoluble carrier ~~in (a) above~~, and said second reagent contains said enzyme inhibitor and said substrate ~~in (b) and (c) above~~.

3. (Currently Amended) An immunoassay reagent for use in quantitative determination of a target antigen or antibody present in a sample, said reagent consisting essentially of the following components:

(a) an insoluble carrier which carries and is coupled to an enzyme inhibitor and an antibody or antigen reactive with said target antigen or antibody, said insoluble carrier comprising at least one selected from the group consisting of an organic polymer powder ~~particle~~ particle, microorganism, blood cell and cell membrane fragment, said insoluble carrier being capable of aggregation;

(b) an enzyme which reacts with and whose enzymatic activity is inhibited by said enzyme

inhibitor, said enzyme being in a free state uncoupled to an antigen or antibody and being increasingly stearically hindered from reacting with said enzyme inhibitor when said insoluble carrier is increasingly aggregated ~~and the reaction between the enzyme and enzyme inhibitor being dependent upon the amount of antigen or antibody present in a sample, and in the presence of an antigen or antibody the insoluble carriers are caused to aggregate, resulting in stearic hindrance of resulting aggregates and reduction of reactions between the enzyme and enzyme inhibitor on the insoluble carrier; and~~

(c) a substrate ~~with which~~ for the enzyme capable of producing an optically detectable indication of reaction with the enzyme reacts;

said components (a)-(c) being maintained separate and apart and sequentially mixed together only with a sample of target antigen or antibody, the addition of the substrate facilitating reaction with the enzyme, thereby effecting an optically detectable change in absorbence.

4. (Cancelled)

5. (Previously Amended) The immunoassay reagent of claim 1, wherein said insoluble carrier further contains a magnetic or magnetizable material.

6. (Cancelled)

7. (Cancelled)

8. (Cancelled)

9. (Previously Amended) The immunoassay reagent of claim 1, wherein said enzyme inhibitor is an antibody against said enzyme.

10. (Original) The immunoassay reagent as recited in claim 9, wherein said antibody against the enzyme is a monoclonal antibody.

11. (Currently Amended) An immunoassay method for quantitatively determining a target antigen or antibody present in a sample, comprising:

first mixing the immunoassay reagent of claim 1 with the sample to thereby facilitate an enzyme reaction and an antigen-antibody reaction resulting in agglutination of the insoluble carrier to form a mixture; and

then measuring the absorbance of ~~resulting~~ said mixture as an index of an amount of target antigen or antibody in the sample.

12. (Original) The immunoassay reagent of claim 3, wherein said insoluble carrier further contains a magnetic or magnetizable material.

14. (Original) The immunoassay reagent of claim 3, wherein said enzyme inhibitor is an antibody against said enzyme.

15. (Original) The immunoassay reagent as recited in claim 14, wherein said antibody against the enzyme is a monoclonal antibody.

16. (Currently Amended) An immunoassay method for quantitatively determining a target antigen or antibody present in a sample, comprising;

sequentially mixing said components (a)-(c) of the immunoassay reagent of claim 3 with a sample suspected of containing a quantity of said target antigen or antibody, wherein a plurality of said insoluble carrier carrying said antibody or antigen reactive with said target antigen or antibody, respectively, are first mixed with the sample under conditions sufficient for a level of agglutination

of the carriers when said target antigen or antibody is present in the sample,

thereafter adding said ~~by first mixing component (a) with a sample containing a target antigen or antibody resulting in aggregations of insoluble carrier, thereafter mixing component (b) to the mixed sample under conditions sufficient for the enzyme to react with said carrier-coupled enzyme inhibitor to a level dependent upon steric hindrance dependent upon the level of agglutination of the carriers,~~

thereafter adding the enzyme substrate to react with the enzyme which has not reacted with the enzyme inhibitor to produce a level of optically detectable signal, and optically determining the level of signal as an indication of the level of agglutination of the carriers indicative of the quantity of the target antigen or antibody in the sample ~~and then component (c), resulting in a change in absorbance based on the amount of target antigen or antibody in the sample, and then measuring the absorbance of resulting mixture as an index of an amount of target antigen or antibody in the sample.~~